K041231

AUG 1 0 2004

1.9 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **To be allocated**

Applicant Information:

Submission Date:	6th May 2004
Date Modified:	5th August 2004
Name:	PANBIO Limited
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Device Information:

Trade Name:	West Nile Virus IgM Capture ELISA
Common Name:	West Nile Virus IgM Capture EIA Test
Classification Name:	West Nile virus, serological reagents (21 CFR 866.3940).

Equivalent Device:
Substantial equivalence to the PANBIO West Nile Virus IgM Capture ELISA (E-WNV01M – 510(k): K031703) is claimed and shall be demonstrated via the enclosed performance data. The PANBIO West Nile Virus IgM Capture ELISA, E-WNV02M, is identical in intended use to the 510(k)-cleared E-WNV01M device. Modifications to the E-WNV02M antigen and conjugate format have resulted in improved performance of the device. The re-designed E-WNV02M device in this submission is intended to supersede the E-WNV01M 510(k)-cleared version on the US market.

Device Description:
The West Nile Virus IgM Capture ELISA is an Enzyme Linked Immunosorbent Assay (ELISA) for the qualitative detection of IgM antibodies to West Nile virus in serum as an aid in the clinical laboratory diagnosis of West Nile virus in patients with clinical symptoms consistent with encephalitis / meningitis.

Intended Use:
The PANBIO West Nile Virus IgM Capture ELISA is for the qualitative presumptive detection of IgM antibodies to West Nile virus in serum as an aid in the clinical laboratory diagnosis of West Nile virus infection in patients with clinical symptoms consistent with encephalitis / meningitis. Positive results must be confirmed by plaque reduction neutralization test (PRNT), or by using the current Centers for Disease Control and Prevention (CDC) guidelines for diagnosis of this disease.

Assay performance characteristics have not been established for testing cord blood, neonate, prenatal screening, general population screening without symptoms of meningioencephalitis or automated instruments. The user is responsible for establishing these assay performance characteristics.

Caution: Cross-reactivity has been noted with the PANBIO West Nile IgM assay in specimens containing rheumatoid factor (RF). Reactive results must be reported with a caution statement regarding possible cross-reactivity with RF.

Principle of Procedure:
Serum antibodies of the IgM class combine with anti-human IgM antibodies attached to the polystyrene surface of the microwell test strips (assay plate). Residual serum is removed from the assay plate by washing. WNV antigen combined with HRP conjugated monoclonal antibody (Mab) is added to the assay plate. After incubation, the microwells are washed and a colorless substrate system, tetramethylbenzidine/hydrogen peroxide (TMB/H_2O_2) is added. The substrate is hydrolyzed by the HRP, if present, and the chromogen changes to a blue color. After stopping the reaction with acid, the TMB becomes yellow. Color development is indicative of the presence of IgM WNV antibodies in the test sample.

PERFORMANCE CHARACTERISTICS

Study Site 1:

Four hundred and twenty (420) retrospective sera from individuals of various ages and both genders were tested at PANBIO. The sera included samples from the following groups: 121 endemic samples from a blood donation center in California, USA; 115 endemic negative specimens from a private reference laboratory in Maryland, USA; 132 specimens from patients presenting for WNV testing at a private reference laboratory in Utah, USA; 26 specimens from patients presenting for WNV testing at a university medical branch in Texas, USA; and 26 specimens from patients presenting for WNV testing from a private laboratory in Minnesota, USA. Of these samples 130 were pre-characterized by PRNT, 73 had CDC MAC EIA results and 419 had IgM IFA ASR results. These samples were subsequently tested on the PANBIO West Nile Virus IgM Capture ELISA to determine assay performance. The data is summarized in Tables 1, 2 and 3.

Table 1 – Study Site 1
Reactivity with PRNT
Serologically Confirmed Specimens

Specimen Characterization [b] (Confirmed by PRNT)	PANBIO IgM ELISA Result			
	Pos	Eqv [a]	Neg	Total
WNV positive	59	0	2 [d]	61
WNV negative	9 [c]	1	59	69
Total	68	1	61	130

Table 2 – Study Site 1
Reactivity with CDC MAC EIA
Presumptively Characterized Specimens

Specimen Characterization [e] (Presumptive by CDC MAC EIA)	PANBIO IgM ELISA Result			
	Pos	Eqv [a]	Neg	Total
WNV positive	11	0	0	11
WNV negative	1	0	61	62
Total	12	0	61	73

Table 3 – Study Site 1
Reactivity with IgM IFA
Presumptively Characterized Specimens

Specimen Characterization [f] (Presumptive by WNV IgM IFA)	PANBIO IgM ELISA Result			
	Pos	Eqv[a]	Neg	Total
WNV positive	86	0	10	96
Indeterminate[g]	7[h]	0	16[i]	23
WNV negative	3	1	296	300
Total	**96**	**1**	**322**	**419**

[a] *Equivocal samples were not repeated.*
[b] *PRNT testing conducted at a blood donation centre in California, USA, and a government medical laboratory in Canada.*
[c] *WNV PRNT negative / PANBIO IgM ELISA positive: Further investigation of the discrepant nature of these samples identified that most (7/9) were presumptively IgM positive (CDC MAC EIA = 2, IgM IFA ASR = 5).*
[d] *WNV PRNT positive / PANBIO IgM ELISA negative: Further investigation of the discrepant nature identified that these samples (n=2) were presumptively IgM negative (CDC MAC EIA = 1, IgM IFA ASR = 1).*
[e] *CDC MAC EIA testing conducted at PANBIO.*
[f] *IFA testing conducted at PANBIO and a private reference laboratory in Utah, USA using the PANBIO IgM IFA ASR.*
[g] *Twenty three (23) samples tested by IFA yielded indeterminate results. This was the product of non-specific staining yielding an unacceptably high background making it not possible to make a reliable interpretation.*
[h] *All 7 sera tested positive by MAC ELISA. All were further characterised by PRNT with 5 yielding a positive reaction and 2 a negative reaction.*
[i] *Fifteen of the 16 sera were tested by MAC ELISA and yielded a negative result. Six of these 15 sera were tested by PRNT and yielded negative reactions. The one sample not tested by MAC ELISA tested negative by PRNT.*

		95% CI*
WNV (confirmed by PRNT)		
Serological sensitivity = 59/61	96.7%	88.7 – 99.6%
Serological specificity = 59/69	85.5%	75.0 – 92.8%
WNV (presumptive by CDC MAC EIA)		
Positive agreement = 11/11	100%	71.5 – 100%
Negative agreement = 61/62	98.4%	91.3 – 100%
WNV (presumptive by IgM IFA)		
Positive agreement[1] = 86/112	76.7%	69.0 - 84.6%
Negative agreement[2] = 296/307	96.4%	93.7 – 98.2%

[1] *The 16 samples testing indeterminate by IFA and negative by the PANBIO WNV IgM were intentionally assigned to the "IgM positive" category for the purpose of this calculation yielding a worst-case scenario.*
[2] *The 7 samples testing indeterminate by IFA and positive by the PANBIO WNV IgM were intentionally assigned to the "IgM negative" category for the purpose of this calculation yielding a worst-case scenario.*
Note: These specimen results were primarily due to nonspecific staining. If indeterminate samples were eliminated from the data set the positive agreement would be 89.6% (CI 81.7 - 94.9%) and the negative agreement 98.7% (CI 96.6 - 99.6%).

*CI = Exact confidence interval

Study Site 2

Fifty-one (51) retrospective sera from patients with symptoms of encephalitis / meningitis, confirmed by PRNT for WNV antibodies, were tested at a hospital laboratory in Ohio, USA. The sera were collected from individuals of various ages and both genders in 2002 and tested in 2004 on the PANBIO West Nile Virus IgM Capture ELISA. The results were compared to the clinical and serological characterization of the specimens to determine the performance of the assay. The data is summarized in Table 4.

Table 4 – Study Site 2
Reactivity with Encephalitis / Meningitis Patient and Endemic Patient Specimens

Specimen Characterization	PANBIO IgM ELISA Result (E-WNV02M)			
	Pos	Eqv	Neg	Total
Encephalitis / meningitis patients (E-WNV01M & PRNT positive)[a]	51	0	0	51

[a] *Encephalitis / meningitis patients: Specimens collected in 2002. Samples were tested by WNV PRNT and further tested on the E-WNV02M device.*

Encephalitis / meningitis patients (documented WNV infection by PRNT)

		95% CI*
Clinical sensitivity (with PRNT) = 51/51	100.0%	93.0 – 100.0%

*CI = Exact confidence interval

An additional six acute serum specimens, without PRNT information, from individuals with signs and symptoms of encephalitis who had evidence of specific anti-WNV IgM being present in CSF were tested. Due to anti-WNV IgM being present in CSF these individuals were considered to have WNV associated-encephalitis. When the serum specimens were tested with the PANBIO WNV IgM test all specimen results were negative.

SPECIFICITY OF IgM DETECTION

A study consisting of 10 serum samples with varying levels of IgM antibodies was conducted to assess the specificity of IgM detection in the PANBIO West Nile Virus IgM Capture ELISA. The samples were treated with 0.005M Dithiothreitol (DTT) to remove IgM antibodies. The un-treated and treated samples were then tested on the PANBIO West Nile Virus IgM Capture ELISA. All DTT treated samples showed a significant decrease in absorbance. A further study consisting of 8 serum samples with known levels of IgM and IgG antibodies to WNV showed no effect on IgM reactivity when these samples were treated with a goat anti-human IgG absorbent. These studies indicate that the assay is specific for IgM antibodies and that specific WNV IgG antibodies do not interfere with the assay.

EFFECTS OF FREEZE-THAW CYCLES

A study consisting of 8 serum samples with varying levels of IgM antibodies to WNV was conducted to determine the effects of multiple freeze-thaw cycles on the detection of WNV IgM antibodies in patient sera. This study indicates that five freeze-thaw cycles have little effect on the detection of IgM antibodies, and therefore it is recommended that samples may undergo up to three freeze-thaw cycles for testing purposes.

REPRODUCIBILITY

The reproducibility of the PANBIO West Nile Virus IgM Capture ELISA was determined by testing 8 sera 3 times each on 3 different assays at one Australian study site and two study sites in the USA. Within-run, between day, between site and total precision were estimated by Analysis of Variance (ANOVA Type II). The results are presented in Table 5 below.

Table 5 – Reproducibility Study (Three Sites)
Precision Measures (Using Index Value*)

			Within		Between Day		Between Site		Total	
Sample	n	*Mean	*S.D	CV	*S.D	CV	*S.D	CV	*S.D	CV
Positive	27	2.63	0.18	7.0%	0.00	0.0%	0.28	10.6%	0.29	11.2%
Cut-off	27	1.00	0.03	2.8%	0.00	0.0%	0.00	0.0%	0.03	2.6%
Negative	27	0.23	0.03	13.7%	0.00	0.0%	0.03	12.3%	0.04	16.8%
#1	27	2.77	0.18	6.6%	0.06	2.3%	0.43	15.7%	0.41	14.7%
#2	27	2.63	0.09	3.5%	0.00	0.0%	0.31	11.9%	0.28	10.5%
#3	27	3.26	0.10	2.9%	0.00	0.0%	0.40	12.4%	0.35	10.7%
#4	27	1.23	0.04	2.8%	0.00	0.0%	0.12	9.4%	0.10	8.3%
#5	27	1.20	0.05	4.3%	0.01	0.6%	0.10	8.6%	0.10	8.3%
#6	27	1.44	0.06	4.1%	0.02	1.6%	0.15	10.1%	0.14	9.5%
#7	27	0.83	0.04	4.7%	0.01	1.0%	0.08	9.6%	0.08	9.3%
#8	27	1.04	0.06	5.3%	0.00	0.0%	0.09	8.7%	0.09	8.9%

All values are calculated from Index values (Cut-Off using O.D)
SD = Standard Deviation; CV = Coefficient of Variation

Note: Standard Deviation results have been rounded to two decimal places for tabulation purposes.
** Index value is calculated by dividing the sample absorbance by the cut-off value.*

CROSS REACTIVITY

This study consisted of a panel of 160 specimens from patients with confirmed diseases other than WNV. The purpose of this study was to establish the analytical specificity of the PANBIO West Nile Virus IgM Capture ELISA through the analysis of specimens from patients with diseases that have the potential for cross-reactivity. Each of the specimens included in the study was characterised with respect to disease state prior to analysis of the specimens with the PANBIO West Nile Virus IgM Capture ELISA. Table 6 below provides a summary of specimens in the disease panel outlined in Table 7.

Table 6 – Summary of Cross-reactivity Study
PANBIO West Nile Virus IgM Capture ELISA
(E-WNV02M)

Disease State	Study Site	PANBIO IgG ELISA Results			
		Pos	Eqv	Total Reactive	
Epstein-Barr virus	1	0	0	0/15	0.0%
Varicella-Zoster virus	1	0	0	0/15	0.0%
Cytomegalovirus	1	0	0	0/15	0.0%
Ross River virus	1	0	0	0/26	0.0%
Enterovirus	1	0	0	0/7	0.0%
Dengue virus	1	2	0	2/16	12.5%
St. Louis encephalitis	1	0	0	0/6	0.0%
La Crosse encephalitis	1, 2 [a]	0	0	0/19	0.0%
Hepatitis A	1	0	0	0/11	0.0%
Anti-Nuclear Antibody	1	0	0	0/15	0.0%
Rheumatoid Factor	1	3	1	4/15	26.7%
Total		5	1	6/160	3.8%

[a] Samples tested in-house at PANBIO except for 9/19 La Crosse encephalitis specimens tested at a hospital laboratory in Ohio, USA.

TABLE 7
Results of Cross-reactivity Study
PANBIO West Nile Virus IgM Capture ELISA
(E-WNV02M)

Sample	Site	IgM Antibody Type	PANBIO E-WNV02M ELISA Result	
			Index	Result
1	1	La Crosse encephalitis	0.47	N
2	1	La Crosse encephalitis	0.28	N
3	1	La Crosse encephalitis	0.34	N
4	1	La Crosse encephalitis	0.26	N
5	1	La Crosse encephalitis	0.31	N
6	1	La Crosse encephalitis	0.30	N
7	1	La Crosse encephalitis	0.58	N
8	1	La Crosse encephalitis	0.38	N
9	1	La Crosse encephalitis	0.31	N
10	1	La Crosse encephalitis	0.37	N
11	2	La Crosse encephalitis	0.39	N
12	2	La Crosse encephalitis	0.34	N
13	2	La Crosse encephalitis	0.38	N
14	2	La Crosse encephalitis	0.32	N
15	2	La Crosse encephalitis	0.45	N
16	2	La Crosse encephalitis	0.25	N
17	2	La Crosse encephalitis	0.24	N
18	2	La Crosse encephalitis	0.30	N
19	2	La Crosse encephalitis	0.25	N
20	1	Saint Louis encephalitis	0.31	N
21	1	Saint Louis encephalitis	0.23	N
22	1	Saint Louis encephalitis	0.21	N
23	1	Saint Louis encephalitis	0.27	N
24	1	Saint Louis encephalitis	0.27	N
25	1	Saint Louis encephalitis	0.23	N
26	1	Rheumatoid Factor	0.18	N
27	1	Rheumatoid Factor	4.84	P
28	1	Rheumatoid Factor	1.86	P
29	1	Rheumatoid Factor	3.76	P
30	1	Rheumatoid Factor	0.25	N
31	1	Rheumatoid Factor	0.33	N
32	1	Rheumatoid Factor	0.98	E
33	1	Rheumatoid Factor	0.41	N
34	1	Rheumatoid Factor	0.34	N
35	1	Rheumatoid Factor	0.61	N
36	1	Rheumatoid Factor	0.36	N
37	1	Rheumatoid Factor	0.24	N
38	1	Rheumatoid Factor	0.54	N
39	1	Rheumatoid Factor	0.44	N

Sample	Site	IgM Antibody Type	PANBIO E-WNV02M ELISA Result	
			Index	Result
40	1	Rheumatoid Factor	0.42	N
41	1	Anti-Nuclear Antibody	0.23	N
42	1	Anti-Nuclear Antibody	0.20	N
43	1	Anti-Nuclear Antibody	0.22	N
44	1	Anti-Nuclear Antibody	0.27	N
45	1	Anti-Nuclear Antibody	0.18	N
46	1	Anti-Nuclear Antibody	0.25	N
47	1	Anti-Nuclear Antibody	0.24	N
48	1	Anti-Nuclear Antibody	0.20	N
49	1	Anti-Nuclear Antibody	0.24	N
50	1	Anti-Nuclear Antibody	0.25	N
51	1	Anti-Nuclear Antibody	0.28	N
52	1	Anti-Nuclear Antibody	0.26	N
53	1	Anti-Nuclear Antibody	0.41	N
54	1	Anti-Nuclear Antibody	0.27	N
55	1	Anti-Nuclear Antibody	0.18	N
56	1	Hepatitis A	0.33	N
57	1	Hepatitis A	0.35	N
58	1	Hepatitis A	0.23	N
59	1	Hepatitis A	0.22	N
60	1	Hepatitis A	0.21	N
61	1	Hepatitis A	0.44	N
62	1	Hepatitis A	0.38	N
63	1	Hepatitis A	0.31	N
64	1	Hepatitis A	0.26	N
65	1	Hepatitis A	0.69	N
66	1	Hepatitis A	0.46	N
67	1	Epstein-Barr virus	0.17	N
68	1	Epstein-Barr virus	0.26	N
69	1	Epstein-Barr virus	0.22	N
70	1	Epstein-Barr virus	0.21	N
71	1	Epstein-Barr virus	0.26	N
72	1	Epstein-Barr virus	0.42	N
73	1	Epstein-Barr virus	0.25	N
74	1	Epstein-Barr virus	0.20	N
75	1	Epstein-Barr virus	0.26	N
76	1	Epstein-Barr virus	0.25	N
77	1	Epstein-Barr virus	0.27	N
78	1	Epstein-Barr virus	0.25	N
79	1	Epstein-Barr virus	0.33	N
80	1	Epstein-Barr virus	0.33	N
81	1	Epstein-Barr virus	0.34	N

Sample	Site	IgM Antibody Type	PANBIO E-WNV02M ELISA Result	
			Index	Result
82	1	Dengue virus	0.59	N
83	1	Dengue virus	0.32	N
84	1	Dengue virus	0.30	N
85	1	Dengue virus	0.36	N
86	1	Dengue virus	0.51	N
87	1	Dengue virus	0.40	N
88	1	Dengue virus	0.33	N
89	1	Dengue virus	1.26	P
90	1	Dengue virus	1.27	P
91	1	Dengue virus	0.37	N
92	1	Dengue virus	0.32	N
93	1	Dengue virus	0.27	N
94	1	Dengue virus	0.30	N
95	1	Dengue virus	0.56	N
96	1	Dengue virus	0.41	N
97	1	Dengue virus	0.48	N
98	1	Cytomegalovirus	0.43	N
99	1	Cytomegalovirus	0.24	N
100	1	Cytomegalovirus	0.27	N
101	1	Cytomegalovirus	0.53	N
102	1	Cytomegalovirus	0.31	N
103	1	Cytomegalovirus	0.51	N
104	1	Cytomegalovirus	0.39	N
105	1	Cytomegalovirus	0.41	N
106	1	Cytomegalovirus	0.34	N
107	1	Cytomegalovirus	0.54	N
108	1	Cytomegalovirus	0.33	N
109	1	Cytomegalovirus	0.22	N
110	1	Cytomegalovirus	0.27	N
111	1	Cytomegalovirus	0.37	N
112	1	Cytomegalovirus	0.52	N
113	1	Varicella-Zoster virus	0.34	N
114	1	Varicella-Zoster virus	0.55	N
115	1	Varicella-Zoster virus	0.23	N
116	1	Varicella-Zoster virus	0.31	N
117	1	Varicella-Zoster virus	0.30	N
118	1	Varicella-Zoster virus	0.23	N
119	1	Varicella-Zoster virus	0.28	N
120	1	Varicella-Zoster virus	0.69	N
121	1	Varicella-Zoster virus	0.24	N
122	1	Varicella-Zoster virus	0.24	N
123	1	Varicella-Zoster virus	0.21	N

Sample	Site	IgM Antibody Type	PANBIO E-WNV02M ELISA Result	
			Index	Result
124	1	Varicella-Zoster virus	0.27	N
125	1	Varicella-Zoster virus	0.31	N
126	1	Varicella-Zoster virus	0.20	N
127	1	Varicella-Zoster virus	0.40	N
128	1	Ross River virus	0.26	N
129	1	Ross River virus	0.28	N
130	1	Ross River virus	0.23	N
131	1	Ross River virus	0.30	N
132	1	Ross River virus	0.24	N
133	1	Ross River virus	0.26	N
134	1	Ross River virus	0.20	N
135	1	Ross River virus	0.17	N
136	1	Ross River virus	0.27	N
137	1	Ross River virus	0.25	N
138	1	Ross River virus	0.60	N
139	1	Ross River virus	0.28	N
140	1	Ross River virus	0.23	N
141	1	Ross River virus	0.19	N
142	1	Ross River virus	0.21	N
143	1	Ross River virus	0.23	N
144	1	Ross River virus	0.39	N
145	1	Ross River virus	0.17	N
146	1	Ross River virus	0.18	N
147	1	Ross River virus	0.21	N
148	1	Ross River virus	0.24	N
149	1	Ross River virus	0.21	N
150	1	Ross River virus	0.27	N
151	1	Ross River virus	0.19	N
152	1	Ross River virus	0.22	N
153	1	Ross River virus	0.15	N
154	1	Enterovirus	0.42	N
155	1	Enterovirus	0.34	N
156	1	Enterovirus	0.27	N
157	1	Enterovirus	0.28	N
158	1	Enterovirus	0.19	N
159	1	Enterovirus	0.27	N
160	1	Enterovirus	0.29	N

INTERPRETATION

ELISA	Positive = P	Equivocal	Negative = N
PANBIO Index	> 1.1	0.9 – 1.1	< 0.9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 0 2004

Ms. Kate Wersin
Regulatory Affairs Officer
PANBIO Limited.
116 Lutwyche Road, Windsor
Brisbane, Queensland 4030
Australia

Re: k041231
Trade/Device Name: West Nile Virus IgM Capture ELISA
Regulation Number: 21 CFR 866.3940
Regulation Name: West Nile Virus Serological Reagents
Regulatory Class: Class II
Product Code: NOP
Dated: May 6, 2004
Received: May 10, 2004

Dear Ms. Wersin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

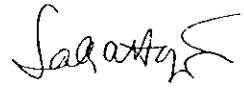
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041231

Device Name: West Nile Virus IgM Capture ELISA

Indications for Use: The PANBIO West Nile Virus IgM Capture ELISA is for the qualitative presumptive detection of IgM antibodies to West Nile virus in serum as an aid in the clinical laboratory diagnosis of West Nile virus infection in patients with clinical symptoms consistent with encephalitis / meningitis. Positive results must be confirmed by plaque reduction neutralization test (PRNT), or by using the current Centers for Disease Control and Prevention (CDC) guidelines for diagnosis of this disease.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) k041231